

ERBE



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Sheet 1 / 2

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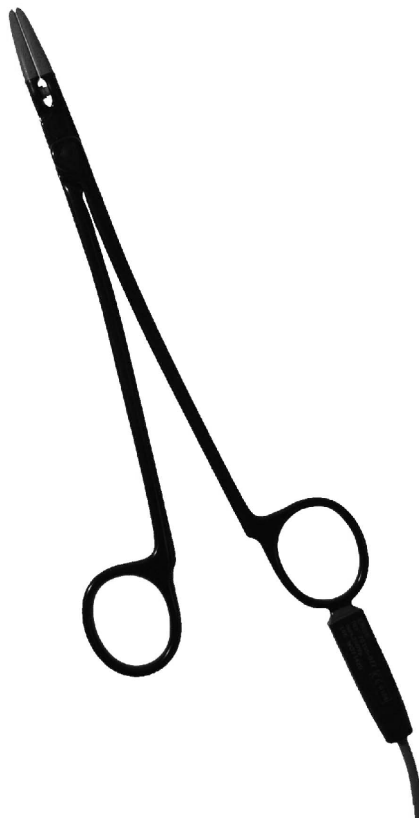


Figure 1. 20195-286.



USA

BiClamp™

Important! Please read all information carefully. These notes on use are not intended as a substitute for the User Manual of the device being used. If in doubt, read the equipment (unit's) User Manual or ask an ERBE representative or your distributor for assistance.

Caution! Federal law (USA) restricts this device to sale by or on the order of a physician!

This product may only be used by trained medical staff who have been instructed in its use on the basis of the notes on use.

Intended Use

The BiClamps are intended for use in general surgery, gynecologic, urological, and thoracic procedures where fusion of vessels or tissues is desired. The devices can be used on vessels up to 7 mm and bundles as large as will fit in the jaws of the instrument. A vessel fusion is created by the application of bipolar electrosurgical RF energy (coagulation) to the vessels placed between the jaws of the instrument.

The BiClamps are designed for use with an ERBE VIO ESU (electrosurgical unit) having an Optional Bipolar Mode/BiClamp upgrade and the multifunctional receptacle. Not recommended for use with other manufacturer's generators.

Indications for Use

The indications for use include general surgery, gynecologic, urological, and thoracic procedures where fusion of vessels and tissue bundles is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), Nissen fundoplication, adhesiolysis (lysis of adhesions), oophorectomy, etc.

Maximum Electrical Capacity

The maximum electrical capacity is shown on the instrument in [V_p].

Safety Instructions

WARNING!

Before each use, check the insulation or coating of the product for damage and look for signs of mechanical damage!

If the cable conductor is broken or the electrical continuity of the cable is interrupted in any other manner it can cause arcing in the patient return system or in the active circuit; this can lead to the patient suffering burns or the outbreak of a fire.

If damaged, do not use this product!

Do not use in the presence of combustible or explosive materials!

Never lay this product on the patient or in his/her direct vicinity.

If subjected to heavy loads (e.g. prolonged high current application due to low contact impedance situations), the jaws will become warm. In order to prevent undesirable coagulations do not touch any tissue with the jaws accidentally.

Protect this product from any form of mechanical damage! Do not throw! Do not use force! If there is a cable, and unless stated otherwise, do not kink it or wrap it around the accompanying product!

ERBE Elektromedizin expressly warns against modifying the product. Any modification exempts ERBE Elektromedizin from any and all liability.

CAUTION!

Vessel fusion can be affected by patient factors such as age, elasticity of vessels, thickness of vessel walls, etc; therefore, the physician should review each vessel fusion for seal integrity.

This device is not effective for use in tubal sterilization/tubal coagulation for sterilization purposes.

Do not use this device on vessels in excess of 7 mm in diameter.

Recommended against the use of electrosurgery for circumcisions.

How to Use

The following factors can shorten the service life of the product considerably:

- scratching/damaging the insulation and/or coagulation sur-

- faces during the operation (e.g. caused by other instruments)
- failure to remove dried coagulation remnants from the surfaces during the operation
- incorrect procedure when cleaning the product during and after the operation

This product possesses an electronic identifier (i.e. the product and its specifications are recognized by the VIO ESU after the connecting cable has been inserted and several default settings are executed automatically on the ESU).

Before Use

Clean/disinfect and sterilize this product before using it for the first time and before every subsequent use.

After setting up the sterile field and just before the procedure, perform an electrical continuity test on the product prior to use. For example, the product can be tested on the sterile field by using a sterile sponge or towel soaked with sterile saline solution.

Before every application, check the coagulation surfaces (i.e. jaws) for signs of damage!

During Use

WARNING! The jaws can become warm if subjected to heavy loads (e.g. prolonged high current application due to low contact impedance situations)! There is a risk of unintentional coagulation if they come into contact with tissue accidentally.

- Avoid accidental contact with tissue.
- Maintain sufficient distance from tissue that is not involved in the operation.

Regularly remove excessive contamination occurring during the operation on the coagulation surfaces and the backs of the jaws (e.g. after every coagulation cycle) with a cloth moistened with sterile water.

For cleaning purposes never use sharp or scouring objects. Scratched/damaged insulation and/or coagulation surfaces restrict operation of the product.

After Use

Preclean the product directly after use (see next chapter).

Cleaning, Disinfection, Sterilization

Safety Instructions

Clean/disinfect and sterilize the product immediately after use.

On no account use sharp or abrasive objects for cleaning purposes.

It is essential to follow the cleaning agent and disinfectant manufacturers' instructions.

Disinfectants must be rinsed off thoroughly after use!

The product can be cleaned/disinfected up to a maximum temperature of 203 °F (95 °C).

The product can be sterilized up to a maximum temperature of 280 °F (138 °C).

Do not sterilize with gamma radiation!

Do not sterilize in hot air oven!

Reconditioning Limitation

The product has been found to work as intended after at least 30 cleaning/disinfection and sterilization cycles.

Recommended Processing Agents/Equipment

The listed cleaning/disinfection agents and sterilization equipment have been validated with the following processing procedures.

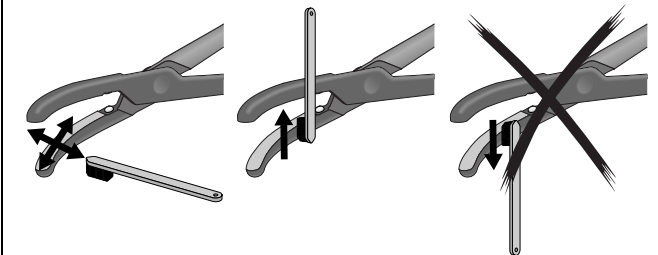
- Manual cleaning/disinfection with the detergent Cidezyme® LF/Enzol and disinfectant Cidex® OPA (Johnson & Johnson Medical Limited, Gargrave, Skipton).
- Cleaning/disinfection by machine in a disinfecter G 7736 CD (Miele & Cie GmbH & Co., Gütersloh/Germany) using neodisher® mediclean forte detergent (Dr. Weigert GmbH & Co. KG, Hamburg/Germany) in accordance with the recommended washing program.
- Autoclave.

Precleaning

Preclean the product up to a maximum of 2 hours after use.

For heavy soiling ERBE Elektromedizin recommends an approx. 3-percent hydrogen peroxide bath.

When using a soft plastic brush, ensure that the brush is moved only in parallel with the coagulation surface of the BiClamp or from the backs of the jaws in the direction towards the coagulation surface. On no account brush from the coagulation surface in the direction of the backs of the jaws. See also the following illustration:





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1. If required, place the product in an approx. 3-percent hydrogen peroxide bath.
2. Carefully remove excessive soiling with a clean soft cloth or a soft plastic brush under running water or using a suitable aldehyde-free disinfectant.

Manual Cleaning and Disinfection

Use a liquid detergent suitable for soaking.

Use a disinfectant compatible with the detergent suitable for soaking.

Cleaning

1. Prepare a cleaning bath according to the manufacturer's directions.
2. Carefully lay the instrument in the cleaning bath, with the jaws of the instrument open, so that it is completely immersed and does not come into contact with other instruments.
3. Leave the instrument in the cleaning bath for the specified action time.
4. If necessary, clean off any still adhering contaminants with a clean, soft cloth or a soft plastic brush.
5. Carefully remove the instrument from the cleaning bath.
6. Flush the instrument thoroughly under running tap water (for at least 1 minute).
7. Rinse the instrument hinge area thoroughly.
8. Dry the instrument lightly using compressed air.
9. Check the instrument for contaminating residues and if necessary repeat the cleaning process.

Disinfection

Only disinfect clean products that have dried slightly.

1. Prepare a disinfectant bath according to the manufacturer's directions.
2. Carefully lay the instrument in the disinfectant bath, with the jaws of the instrument open, so that it is completely immersed and does not come into contact with other instruments.
3. Leave the instrument in the disinfectant bath for the specified action time.
4. Carefully remove the instrument from the disinfectant bath.
5. Flush the instrument thoroughly with sterile distilled water.
6. Dry the instrument thoroughly using compressed air.

Cleaning and Disinfection by Machine

1. Carefully place the instrument with open jaws in a suitable rinsing basket. Ensure that instruments do not contact one another.
2. Start a tested program with the following properties:
 - If possible: thermal disinfection at 199° F (93 °C) for at least 10 minutes.
 - Final rinse with distilled or deionized water.
 - Sufficient product drying.
3. Remove the instrument from the disinfector directly after the end of the program.

Check

1. Check the product for visible damage and wear:
 - Damage to the product, e.g. cracks, rough surface, splintering.
 - Damage to the product insulation and/or cable/connector insulation, e.g. cracks and breaks.
 - Damage to the coating.
 - Bending of the product or parts of the product. Do not attempt to straighten bent parts!

If damaged, do not use this product!

Packaging

The product must be protected against damage during sterilization.

1. Pack the product in disposable sterilization packaging (single or double packaging) made from paper/polyethylene and/or in a sterilization container.

Sterilization

Only sterilize products that have been cleaned/disinfected.

Please follow the sterilizer manufacturer's recommendations on loading and handling instruments for the autoclave process.

ERBE Elektromedizin recommends steam sterilization with the methods described below. If other sterilization methods are used, ERBE Elektromedizin shall bear no responsibility.

Steam

Fractionated vacuum method, holding time 5 minutes at 273 °F to 280 °F (134 °C to 138 °C).

Gravitation method, holding time 8 minutes at 270 °F to 273 °F (132 °C to 134 °C).